K080212

Section E - 510(k) Summary

This 510(k) summary for the **Medela® THOPAZ Suction Pump** meets the requirements of 21 CFR 807.92.

JUL 23 2008

1 Sponsor's Name, Address and Contact Person

Sponsor:
Medela AG
Medical Equipment
Laettichstrasse 4b
6341 Baar
Switzerland
Ph: +41 41 769 5151 ext. 247
Fax: +41 41 769 5100

Contact Person
Bruno Gretler
Manager Regulatory Affairs

Date Summary Prepared: January 24, 2008

2 Name of Device

Trade Name:	**Medela® THOPAZ** Secretion & Surgical Aspirator
Common Name:	Powered Suction Pump
Classification Name:	PUMP, PORTABLE, ASPIRATION (MANUAL OR POWERED) Classified Class II, per 21 CFR 878.4780
Product Code:	BTA

3 Name of the predicate Device(s)

- Medela® Vario 8/18/ci Suction Pumps, by Medela Inc.
  K061205
- Medela® Dominant 35 c/i Suction Pump, by Medela AG
  K043544

4 Device Description

The **Medela® THOPAZ** pump is an innovative secretion aspirator intended to be used for thoracic drainage. Its well-proven membrane system guarantees maximum suction performance and quiet, dependable operation. Additional advantages of the **Medela® THOPAZ** are: user friendliness, patient mobility, simple cleaning and integrated safety features. A comprehensive range of accessories makes the **Medela® THOPAZ** ideally suited for thoracic drainage while mobilizing the patient.

The **Medela® THOPAZ** suction pump is an AC/DC powered, maintenance-free aspirator which incorporates a DC-motor with membrane aggregate power actuation in its housing. A user friendly MMI (man machine interface) guides the user through first installation, change of settings, use, data transfer and alarm handling.

The **Medela® THOPAZ** suction pump has an electronic measuring and monitoring system with optical and acoustic status display. The device is a dry system, which means that no fluids are necessary for operation. Important information about the course of therapy is displayed digitally and as graphics in the display. These data can be transferred to a PC upon completion of the therapy.

The **Medela® THOPAZ** suction pump has a suction capacity of 5 liters per minute and a maximum vacuum up to -10 kPa (-75 mmHg). The pump is marked "low flow – low vacuum".

A variety of reusable and disposable accessories for thoracic drainage are available.

5 Indications for use

The **Medela® THOPAZ** Suction Pump is indicated for aspiration and removal of surgical fluids, tissue, gases, bodily fluids or infectious materials from a patient's respiratory support system (after surgery).

Generally the **Medela® THOPAZ** is intended to be used in all situations where chest drains are applied - especially for thoracic drainage and in situations such as pneumothorax, after surgery (post operative), thorax injury, pleura effusion, pleuryempyem or other related conditions.

6 Summary of Technological Characteristics

The **Medela® THOPAZ** has the same performance characteristics as the predicate devices. These differences regarding type of aggregate and display are marginal and state of the art today. Other FDA approved devices using the same technology (aggregate and display).

The **Medela® THOPAZ** Suction Pump is equipped with the identical technology like other marketed devices. These technological features do not affect safety and effectiveness of the device or the application (thoracic drainage).

7 Conclusion

There are no differences in performance or technology which significantly affect the safety and effectiveness of the device or the application (thoracic drainage). All conclusions are made by the decision making process according to the recommendations in the "510(k) SE Decision Making Process" document.

The **Medela® THOPAZ** suction pump has the identical intended uses and, where applicable, the identical technological characteristics and performance data as the predicate devices.

Based upon the information presented in this submission, it is proven that the proposed **Medela® THOPAZ** powered suction pump is substantially equivalent, safe and effective for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medela AG
% Mr. Bruno Gretler
Manager Regulatory Affairs
Laettichstrasse 4b
6341 Baar
Switzerland

JUL 23 2008

Re: K080212
Trade/Device Name: Medela THOPAZ
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: BTA
Dated: July 10, 2008
Received: July 10, 2008

Dear Mr. Gretler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080212

Device Name: Medela THOPAZ

The Medela THOPAZ Suction Pump is indicated for aspiration and removal of surgical fluids, tissue, gases, bodily fluids or infectious materials from a patient's respiratory support system (after surgery).

Generally the Medela THOPAZ is intended to be used in all situations where chest drains are applied - especially for thoracic drainage and in situations such as pneumothorax, after surgery (post operative), thorax injury, pleura effusion, pleuryempyem or other related conditions.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080212